JUL 2 1 2005

K051053

510(k) Summary

Orthosonics OSCAR OE3000DB

Common:	Ultrasonic Surgical Instrument
Classification Name:	Instrument, Surgical, Sonic and Accessories/Attachments (21 C.F.R. 888.4580)
Sponsor:	Orthosonics Ltd Bremridge Ashburton Devon TQ13 7JX T: +44 1364 652426 F: +44 1364 653589
Contact:	Dr. Michael J. R. Young
Prepared:	April 25, 2005

A. REASON FOR SUBMISSION

This 510(k) is being filed for two main reasons. Firstly, it is to cover improvements in the existing OSCAR (K961725, K021502) which includes a new digital tuning module and new single use probes. Secondly there is a change to the intended use that now includes the cutting and removal of bone via an additional, optional handset.

B. LEGALLY MARKETED PREDICATE DEVICES

The Orthosonics OSCAR OE3000DB is substantially equivalent to the Biomet Ultra-Drive® 3 (K031280), and the Orthosonics OSCAR (K961725, K021502).

C. DEVICE DESCRIPTION

The Orthosonics OSCAR OE3000DB consists of a power module which generates the ultrasonic energy and provides overall control of the device, 2 different handsets; one for acrylic bone cement removal and the other for the cutting and removal of bone, and a variety of probes and other accessories. Three independent power modules are mounted in a cart for ease of use.

D. INTENDED USE

The Orthosonics OSCAR OE3000DB is intended to be used for cutting and removal of bone and acrylic bone cement in orthopaedic applications.

E. SUBSTANTIAL EQUIVALENCE SUMMARY

The Orthosonics OSCAR OE3000DB is a medical device, and it has the same indications for use and target population as the legally marketed predicate device.

The Orthosonics OSCAR OE3000DB has the same technological characteristics as the predicate device. However, the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, performance testing was carried out for some characteristics. The data from this testing was available and was presented in this 510(k).

F. TECHNOLOGICAL CHARACTERISTICS

The basic technological characteristics of the OSCAR OE3000DB device are the same as those of the predicate devices.

G. TESTING

Testing to electrical/ safety standards was successfully carried out. Biocompatibility issues were covered by the OSCAR (K961725) application. Performance testing was carried out in an animal study and the results are included in this 510(k).

H. CONCLUSIONS

This premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2005

Orthosonics
c/o T. Whit Athey, Ph.D.
Health Policy Resources Group, LLC
2305 Gold Mine Road
Brookeville, Maryland 20833

Re: K051053
Trade/Device Name: OSCAR OE3000DB
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachments
Regulatory Class: II
Product Code: JDX, and LZV
Dated: April 25, 2005
Received: April 25, 2005

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
for Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051053

Device Name: OSCAR OE3000DB

Indications For Use:

The **Orthosonics OSCAR OE3000DB** is intended to be used for cutting and removal of bone and acrylic bone cement in orthopedic applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of [illegible] Restorative
and Neurological Devices
510(k) Number K051053